UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,293	09/14/2000	Catherine A. McCall	AL-2-C4	9793

26949 7590 03/04/2005

HESKA CORPORATION
INTELLECTUAL PROPERTY DEPT.
1613 PROSPECT PARKWAY
FORT COLLINS, CO 80525

EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,293	MCCALL ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-57 and 60-65* is/are rejected.

7)☒ Claim(s) *58 and 59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 52-65 are pending.

2. The after-final received 11-10-04 has been entered. A new Non-Final office action is set forth below. All previous rejections of record have been removed.

3. It is noted applicant's Terminal disclaimer filed 11-10-04 has been entered and approved

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 52-57 and 60-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO. 15 or 18 or 21, does not reasonably provide enablement for any Dermatophagoides farinae map B protein that binds to an antibody that selectively binds to SEQ ID NO. 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has isolated a protein, SEQ ID NO. 15., that is exactly the same as SEQ ID NO. 18 and minus a signal sequence is the same as SEQ ID NO. 21. SEQ ID NO. 15 has been demonstrated to bind IgE from dogs allergic to dust mites. The intended use of this one protein is to detect mite allergy and be useful in treating mite allergy by hyposensitization therapy. The ability of the isolated SEQ ID NO. 15 to perform this function is predicated on its ability to bind antibodies found in allergic individuals or induce IgG antibodies upon administration in hyposensitization therapy. Either use requires specific antibody binding based upon the epitopes found in the protein antigen.

The scope of applicant's base claims includes proteins that potentially have unrelated function and only have the ability to bind an antibody originally made against SEQ ID NO. 15. Antibodies against SEQ ID NO. 15 could bind multiple unrelated antigens because of the ability of antibodies to cross react with an unrelated antigen that have an identical epitope, as taught by

Kuby et al. (page 125 in particular). These unrelated antigens have no use in detecting allergy or in treating allergy since they are possibly not related to SEQ ID NO. 15 in function only in epitope characteristic. Applicant has no working examples demonstrating any other protein other SEQ ID NO. 15, can bind to an antibody that specifically binds SEQ ID NO. 15 and has use in either detecting or treating allergy in patients. Further Applicant's specification has no guidance demonstrating what the sequence of the IgE epitopes are in SEQ ID No. 15, or which epitopes can be used to induce hyposensitization in mite allergy from SEQ ID NO. 15. As such it is unclear which unrelated antigens encompassed by the claims can be used in applicants invention and it would require an undue amount of experimentation to determine which ones could or could not be used to practice the full scope of the claimed invention as presently recited.

Further, in claims 53, 54, 55, 56, 57, and 60-65, the claims encompass using protein wherein additional amino acid sequences are added to fragments of SEQ ID NO. 15 (i.e. SEQ ID Nos 1-11) or wherein proteins are used that are 90 or 95% identical to SEQ ID NOS 1-11 are used in diagnosis or treatment. The problem with enabling the scope of these claims is that when you change an amino acid sequence in an epitope or even outside the epitope of the antigen used to generate antibodies the resulting antibodies will likely not bind to original antigen. The specification has demonstrated that SEQ ID NO. 15 is useful in diagnosing and potentially treating mite allergy, however the claims encompass making mutants of the original epitopes. These mutants will not predictably create antibodies that recognize the original antigen, SEQ ID NO. 15, and as such will not be useful in diagnosis and therapy of mite allergy. Colman et al., specifically teaches that amino acid sequence changes in original antigen, effectively abolish antigen antibody binding (page 33 in particular). James et al., specifically teaches that substitution experiments in antigens have shown that changing one amino can reduce reactivity of a sequence by more than 90% (page 2078, 2nd column, 4th full paragraph). Abaza et al., specifically that even changes amino acid sequences outside of epitope can drastically effect the ability of the antibody to bind the antigen (see abstract in particular).

Since, Applicant has no working examples demonstrating which amino sequences can be changed and retain antibody binding specificity to the original antigen and the state of the prior art teaches that antigen mutants do not retain antibody specificity to the original antigen, it would

be unpredictable and require an undue amount of experimentation to practice the full scope of the claimed invention as presently recited.

5. It is noted claims 58 and 59 are objected to as being dependent upon rejected claims.

6. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
February 28, 2005